PATENT APPLICATION

"Express Mail" Mailing label number EV389959205USUS

Date of Deposit December 31, 2003

I hereby certify that this paper or fee is being deposited with the United States Postal Service "EXPRESS MAIL POST OFFICE TO ADDRESSEE" Service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to the Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Michael D. Beck
Name of person mailing Document or Fee

Michael D. Beck
Signature of person mailing Document or Fee

Applicant(s):

Lawrence Boyd
25 Birnham Lane
Durham, NC 27707

Tyler P. Lipschultz
6112 Avalon Drive East
New Canaan, CT 06840

Mark D. LoGuidice
621 Warner Hill Road
Southport, CT 06890-3040

Andrew Carter
9R Conant Street
Acton, MA 01720

DYNAMIC SPINAL STABILIZATION SYTEM

Michael D. Beck
Registration No. 32,722
Attorney Docket No. 1842-0021

Correspondence Address:
Maginot, Moore & Beck, LLP
Bank One Center/Tower
111 Monument Circle, Suite 3000
Indianapolis, Indiana 46204-5115
Telephone: (317)638-2922
Facsimile: (317)638-2139

DYNAMIC SPINAL STABILIZATION SYSTEM

The present invention relates to spinal implant systems, and particularly systems for stabilization of the spine. The invention provides a dynamic stabilization system that permits limited relative movement between the instrumented vertebrae and the stabilization system.

In the past, the principal protocol for the treatment of the spine has been rigid fixation combined with fusion of the affected vertebral body or intervertebral disc. Arthrodesis, as this approach is known, has been achieved with a variety of rigid fixation elements, such as spinal rods or plates that are rigidly fixed to a vertebra using bone screws, bone bolts and spinal hooks. However, spinal fusion has been recognized to have limitations in the treatment of disc degeneration, especially in the earlier stages of the degeneration where it may be unnecessary to eliminate motion of the spinal motion segments.

Clinical studies suggest that cells of the intervertebral disc respond favorably to reduced (but not eliminated) mechanical loading through deposition of extracellular matrix proteins (collagen, proteoglycan, fibronectin, etc.) into the disc space. In some cases, a degenerated disc may simply involve a mechanically overloaded and hypermobile segment that can be repaired by reversing the mechanically damaging load environment. For instance, clinical experiences with dynamic stabilization systems suggest that the disc becomes increasingly hydrated over time, as judged by MRI scanning.

Spinal instability is a recognized effect of degenerative disc disease. In contrast to arthrodesis, arthroplasty is a protocol that contemplates restoring segmental spinal motion while treating the degenerative condition. Arthroplasty has been successfully used in the treatment of degenerative conditions of the hip and knee. In recent years, efforts have been made to implement arthroplasty in the spine, and most particularly in the intervertebral space. Intradiscal arthroplasty is now clinically available in the form of articulating prosthetic discs and polymeric disc nucleus replacements. With the availability of viable

intradiscal arthroplasty devices, interest has grown in providing some means for dynamic spinal stabilization – i.e., stabilization that still permits some degree of mobility between spinal segments.

Drawing from the approaches developed for intradiscal arthroplasty, efforts have made to develop an extradiscal arthroplasty. These systems offer the advantage of "soft stabilization" that limit, rather than eliminate, spinal segment motion. Current theories suggest that preventing movement of the spinal segments may not be a significant factor in clinical success of spinal stabilization systems. Instead, these theories focus on creating a normal loading pattern for the spine as a primary vehicle for successful spinal instrumentation. Thus, the goals for dynamic stabilization has been to restrict movement of the spine to a zone or range where normal or near normal loading of the spinal segments can occur. At the same time, dynamic stabilization techniques have sought to prevent the spine from adopting a position or orientation where abnormal loading of the spine can occur.

One approach to achieve these goals for dynamic stabilization utilizes the spinous process. Thus, in one system, flexible "ligaments' are engaged around the spinous process of adjacent vertebrae. Another form of flexible "ligament" is attached to the spinous process by way of small screws. In yet another approach, a polymeric spacer is held in place between the adjacent spinous processes. One system utilizes a coil spring that spans several vertebrae and that is anchored to the lamina of the end vertebrae. In one version, a rod extends through part of the coil spring to control rotation.

Some dynamic stabilization systems have relied upon fixation to the pedicle of the vertebrae. In these types of systems, a pedicle screw is threaded into the pedicle of adjacent vertebrae. A member spans between the heads of the pedicle screws to limit the movement of the spinal segments. In one device, known as the Graf Ligament, a non-elastic band is wrapped around pedicle screw anchors. The non-elastic bands lock the spinal segment into lordosis, while permitting minimal rotation movements of the spine.

Another system utilizing pedicle screws, known as the Dynesys System, incorporates a polymeric cylinder between the bone anchors. The Dynesys System permits, but limits, relative motion between adjacent vertebrae. The FASS System essentially integrates features from the Graf and Dynesis systems.

The DSS System employs still another approach by including a spring element connected to pedicle screws. The spring element is contained within a polyurethane tube to prevent tissue ingrowth. Finally, some systems utilize a rigid member, such as a spinal plate, spanning between vertebrae. The flexible stabilization feature is incorporated into the interface between the pedicle screw and the rigid member, such as through a flexible washer or a spherical screw-plate interface.

These prior extradiscal arthroplasty approaches all involve the introduction of flexible elements between spinal motion segments. Consequently, many of these systems are susceptible to over-loading the disc annulus or are, by necessity, unduly restrictive with respect to motion of the spinal segment.

Moreover, these prior systems are not capable of altering the stiffness of a segment in various loading modes (e.g., flexion/extension, compression, lateral bending and axial rotation). Furthermore, these early approaches to arthrodesis do not allow selection of where, or at which motion segment, dynamic movement is permitted. Finally, no system exists that can readily convert to and from a soft stabilization to a more rigid or completely rigid system.

SUMMARY OF THE INVENTION

In order to address some of the difficulties associated with prior dynamic stabilization systems, the present invention contemplates a novel bone anchor for use in the stabilization of motion segments of the spine. In a preferred embodiment, the bone anchor comprises an engagement portion configured for engagement within a spinal motion segment and a head portion configured for engagement to a stabilization element outside the vertebral body. The engagement portion can be of many known forms, such as bone screw, bone bolt or spinal hook. The head portion can also assume a variety of known configurations depending upon the type of stabilization element being utilized for the construct. For instance, the stabilization element can be a spinal rod or an elongated plate. The head portion can be configured to engage either type of stabilization element.

In an important feature of this embodiment of the invention, the bone anchor further comprises a flexible portion between the shank and the head portion. The flexible portion permits movement of the head portion relative to the engagement portion when both portions are fixed to the stabilization element and the vertebral body, respectively. In certain embodiments, the flexible portion is arranged to reside substantially extra-pedicular when the bone anchor is engaged within the pedicle of a vertebra. The flexible portion is configured to limit the relative movement between the head portion and the engagement portion to a single plane, most typically a plane parallel to the sagittal plane through the spine.

In one embodiment, the flexible portion includes an elongated body spanning between the engagement portion and the head portion. The elongated body defines at least one hinge element, and preferably several such hinge elements. The hinge element includes a slot defined in the elongated body having an axis substantially transverse to the longitudinal axis of the body. Several hinge elements can be arranged in alternating opposing relation along

the length of the body. To reduce stress risers, each slot terminates within the elongated body with a bore substantially perpendicular to the axis of the slot.

In an alternative embodiment, the flexible portion includes a helical spring disposed between the engagement portion and the head portion. The spring can be constrained to deflect in a predetermined plane or planes.

In a further embodiment, the flexible portion includes an elongated flexible element disposed between the engagement portion and the head portion. The flexible element is a flexible sleeve or a similar tube-like structure spanning between the head and engagement portions. In one configuration, the engagement portion includes an elongated shank, and the elongated shank and the flexible sleeve have substantially equal outer diameters. Moreover, the elongated shank and the flexible sleeve can be configured for interlocking engagement.

The flexible sleeve may be affixed to the head and engagement portions. Alternatively, a tension element may be provided that is anchored at one end to the engagement portion and at an opposite end to the head portion. The tension element extends through the flexible sleeve to clamp the sleeve between the head portion and the engagement portion.

In one embodiment, the tension element is a cable. With this embodiment, the engagement portion includes an elongated shank that defines a longitudinal bore, opening at a proximal and an opposite distal end of the shank. The flexible element and the head portion also define a respective bore therethrough aligned with the longitudinal bore. The cable is then anchored to the shank at the distal end and extends through the longitudinal bore and the bores in the flexible element and the head portion. The cable anchor can be accomplished by the cable including an enlarged head relative to the diameter of the longitudinal bore at the distal end of the shank.

In yet another embodiment of the invention, the bone anchor includes an engagement portion having an elongated shank, in which at least the shank and

the flexible portion are integral. The flexible portion defines a cross-sectional area along the longitudinal axis of the shank that is substantially less than the cross-sectional area of the shank along the longitudinal axis. Thus, the flexible portion will exhibit bending tendencies in the region of the reduced cross section. This bone anchor comprises means surrounding the flexible portion for preventing bone overgrowth at the flexible portion.

To achieve the reduced cross sectional area, the flexible portion has a first dimension in a first plane passing through the bone anchor that is less than a dimension of the engagement portion in the first plane. In certain embodiments, the flexible portion has a second dimension in a second plane substantially transverse to the first plane that is greater than the first dimension. With this configuration, the bone anchor exhibits greater flexibility in the first plane than in the second plane. In still other embodiments, the second dimension of the flexible portion is also greater than a dimension of the engagement portion in the second plane.

An alternative embodiment of the inventive bone anchor utilizes a flexible portion that includes an elongated body spanning between the engagement portion and the head portion, in which the elongated body defines an elongated slot therethrough. The slot extends generally parallel to the longitudinal axis of the elongated body in a sort of "clothes pin" configuration. Preferably, the elongated slot originates in the head portion and extends toward the engagement portion.

The present invention further contemplates a dynamic spinal stabilization system comprising a stabilization element configured to span a length of the spine adjacent the vertebrae and at least one bone anchor having a flexible intermediate portion and at least one other anchor selected from the group including a bone anchor having a flexible intermediate portion, a spinal hook having a hook portion configured to engage a portion of a vertebra and a head portion configured to engage the stabilization element, and a substantially rigid

bone screw having a threaded portion configured to engage a portion of a vertebra and a head portion configured to engage the stabilization element.

The stabilization element can be an elongated plate defining at least two openings therethrough for receiving a corresponding one of the bone anchors. In this case, the head portion of the bone anchors can include a substantially spherical surface, while the elongated plate can define a substantially spherical recess at each of the openings.

The present invention further contemplates a method for dynamic stabilization of motion segments of the spine comprising the steps of:

1) positioning a stabilization element adjacent the spine, the stabilization element configured to span a length of the spine between at least two motion segments;

2) engaging bone anchors to at least two motion segments; and

3) coupling the bone anchors to the stabilization element, with at least one of the bone anchors coupled to permit deflection of the bone anchor between the stabilization element and the motion segment.

This method may be performed in conjunction with repairing or replacing all or part of the intervertebral disc between at least two motion segments.

Another inventive method dynamic stabilization of motion segments of the spine comprises the steps of:

1) positioning a stabilization element adjacent the spine, the stabilization element configured to span a length of the spine between at least two motion segments;

2) engaging bone anchors to at least two motion segments; and

3) coupling the bone anchors to the stabilization element, with at least one of the bone anchors configured to produce a center of rotation for the motion segment between the stabilization element and the normal anatomic center of rotation for the motion segment.

The present invention contemplates improvements to a method for correction of scoliosis in which a contoured rod is engaged to at least a portion of the deformed spine and is rotated to de-rotate the spine in the transverse plane. In particular, the improvement comprises engaging at least one vertebrae at either or both the superior and inferior ends of the rod to the rod to provide a center of rotation for the at least one vertebra that is between the rod and the normal anatomic center of rotation for the vertebra.

The invention also provides improvements to a method for correction of spondylolisthesis in which a slipped vertebra is pulled posteriorly to a stabilization element engaged to spinal elements adjacent the slipped vertebra. This improvement comprises engaging a bone anchor to the slipped vertebra that is configured to be pulled toward the stabilization element and that is configured to provide a center of rotation for the slipped vertebra that is between the stabilization element and the normal anatomic center of rotation for the vertebra.

It is one object of the invention to provide devices and methods that permit improved dynamic stabilization of the spine. A further object resides in features of the invention that allow tailoring of the flexibility at each instrumented spinal motion segment. Other objects and certain benefits of the invention will be appreciated from the following written description of the preferred embodiments, taken together with the accompanying figures.

DESCRIPTION OF THE FIGURES

FIG. 1 is an elevational view of a bone anchor in accordance with one embodiment of the present invention.

FIGS. 2a-2b are enlarged views of alternative embodiments for the flexible portion for the bone anchor shown in **FIG. 1**.

FIG. 3 is a side view of a dynamic stabilization system for implantation into a portion of the spine utilizing the bone anchor shown in **FIG. 1**.

FIGS. 4a-4c are alternative configurations for the head portion of the bone anchor shown in **FIG. 1**.

FIG. 5 is a perspective view of a known spinal plate for use with the bone anchor shown in **FIG. 1**.

FIGS. 6a-6b are enlarged partial cross-sectional views of alternative head portions for use with the bone anchor shown in **FIG. 1**, engaged to the spinal plate shown in **FIG. 5**.

FIG. 7 is an elevational view of a bone anchor in accordance with another embodiment of the present invention.

FIGS. 8a-8b are enlarged views of flexible portions for use with the bone anchor shown in **FIG. 7**.

FIG. 9 is a view of a vertebra instrumented with bone anchors as shown in **FIG. 8** and a spinal plate as shown in **FIG. 5**.

FIG. 10 is an elevational view of a bone anchor in accordance with a further embodiment of the invention.

FIG. 11 is an enlarged view of an alternative flexible portion for the bone anchor shown in **FIG. 10**.

FIG. 12 is a cross-sectional view of the bone anchor shown in **FIG. 10**, taken along line A-A as viewed in the direction of the arrows.

FIG. 13 is a front view of a bone anchor according to a further embodiment of the invention.

FIG. 14 is a side view of the bone anchor shown in **FIG. 13**.

FIG. 15 is a front cross-sectional view of a clamp for engaging the head portion of the bone anchor shown in **FIGS. 13** and **14**.

FIGS. 16a-16b are schematic representations of a scoliotic spine before correction using a rod de-rotation technique, showing the rod from an A/P and a lateral view.

FIGS. 17a-17b are schematic representations of the spine after de-rotation.

FIG. 18 is a lateral schematic representation of a correction for spondylolisthesis.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same should be considered as illustrative and not restrictive in character. It is understood that only the preferred embodiments have been presented and that all changes, modifications and further applications that come within the spirit of the invention are desired to be protected.

The present invention contemplates a bone fastener or anchor that is configured to engage a portion of a vertebra and to connect to a stabilization element adapted to span across a spinal motion segment. The bone anchor includes a flexible portion between the vertebra and the stabilization element that permits limited movement of the instrumented vertebrae without commensurate movement of the stabilization element.

In accordance with one embodiment of the invention shown in **FIG. 1**, a bone anchor **10** is provided that has an engagement portion **12** which may be an elongated shank with external threads **14** configured for engagement within a vertebra. The shank **12** and threads **14** are sized and configured for engagement within any portion of the vertebra, such as the pedicle or vertebral body. Preferably, the threads are configured for anchoring within the cancellous bone of the vertebra.

For the purposes of illustrating the present invention, the bone engagement portion of the anchor has been described as a bone screw or bolt configuration. However, it is understood that other devices for engaging a spinal motion segment or vertebra are contemplated, such as a spinal hook. Moreover, it is understood that the configuration of the elongated shank can be modified, for instance to promote bone ingrowth, or to permit implantation within the intradiscal space.

The anchor **10** includes a head portion **16** that is configured to engage a stabilization member spanning between adjacent vertebrae. As explained in

detail herein, the head portion **16** can assume a variety of configurations depending upon the configuration of the stabilization member.

In one feature of the invention, the anchor **10** includes a flexible portion **18** interposed between the head portion **16** and the engagement portion **12**. In the embodiment depicted in **FIG. 1**, this flexible portion **18** includes one or more hinge elements **20**. More particularly, in the specific embodiment the hinge elements include elements **20a** oriented in one direction relative to the longitudinal axis **L** of the anchor, and elements **20b** in an opposing orientation. These hinge elements **20** represent a region of reduced bending stiffness that permits localized bending about the hinge element. It is thus contemplated that this localized bending will act to open or close the hinge elements, depending upon the direction of movement of the head portion **16** relative to the engagement portion **12**, as represented by the curved arrows in **FIG. 1**.

The number, size and arrangement of the hinge elements **20** may be modified depending upon the amount of bending flexibility that is desired for the particular spinal stabilization. For instance, fewer hinges result in a stiffer bone anchor than a greater number of hinges. In addition, the width of the mouth of the slots will determine the range of bending movement of the flexible portion **18**. In other words, a wider hinge element will be capable of a greater angular range of movement than a narrower hinge element.

Two exemplary hinge configurations are shown in **FIGS. 2a** and **2b**. In one specific embodiment shown in **FIG. 2a**, the hinge elements **20a** and **20b** are defined by slots **21** cut into the bone anchor perpendicular to its longitudinal axis. Each slot **21** terminates in a bore **22** that is most preferably formed along a circumference of the bone anchor. The bores **22** help limit the occurrence of stress risers at the interior of the slots, and may also improve the bending characteristics of the hinge element **20a, 20b**.

In the specific embodiment shown in **FIG. 2b**, the hinge elements **20'** of the flexible portion **18'** are in the form of curved slots. Moreover, the elements **20'** are aligned at a non-perpendicular angle relative to the longitudinal axis of

the anchor. As shown in **FIG. 2b**, each hinge element **20'** is shown with one slot **23a** extending past the center of the flexible portion **18'** and an adjacent shorter slot **23b**. The configuration of **FIG. 2b** allows the slots **23a**, **23b** to be thinner in width than the slots **21** of the embodiment in **FIG. 2a**, while achieving substantially the same degree of bending movement.

Referring to **FIG. 3**, one form of dynamic stabilization system is shown using the bone anchor **10** shown in **FIG. 1**. In particular, the engagement portion **12** of two anchors are engaged within adjacent vertebrae V_1 and V_2. Preferably, the anchors are threaded into the pedicle P of each vertebra. In accordance with the preferred embodiment, the anchors **10** are threaded into the pedicle to a depth where the flexible portions **18** are outside the pedicle so that the anchor can deflect through its full range of angular motion. However, the anchor may be embedded within the vertebra to a depth that encompasses part of the flexible portion **18**. It is contemplated in this circumstance that the amount of bending flexibility of the bone anchor **10** may be calibrated by embedding one or more hinge elements, thereby preventing bending of the anchor about that hinge element.

In an alternative embodiment, the bone anchor **10** can include a bore **24**, as shown in dashed lines in **FIG. 1**, which extends along the axis **L** of the anchor. The bore **24** is configured to receive a stiffening rod (not shown) that can be placed within the bore to essentially convert the anchor into a substantially rigid fastener. The rod can have a length sufficient to fill substantially the entire bore **24**, or can have a shorter length. Where the rod has a shorter length, it will traverse less than all of the hinge elements **20**. Thus, the rod can prevent deflection of the anchor at the lowermost hinge elements, such as elements **20a**, **20b** in **FIG. 1**, while the upper most hinge elements are unencumbered.

As with any spinal implant, fatigue resistance is an important property of the bone anchors of the present invention, such as anchor **10**. Thus, the implant can be formed of accepted medical grade materials, such as stainless steel, or other materials, such as polymers, composites or super-elastic alloys, that exhibit

sufficient fatigue resistance under normal spinal loading conditions and load cycles. Preferably, the hinge elements **20** are configured to minimize stress concentrations, such as through the use of radiused corners. Furthermore, the material can be strengthened during the manufacturing process, such as by minimizing surface roughness, pre-treating the surface (e.g., Ti nitriding, chroming), or pre-stressing the surface (e.g., by shot-peening).

As indicated above, each bone anchor includes a head portion **16** that is configured to engage a stabilization element, such as the element **25** shown in **FIG. 3**. The stabilization element can be an elongated rod or a spinal plate. The head portion **16** is configured appropriately for the specific type of stabilization element **25**. When the dynamic stabilization construct is complete, load applied to the vertebrae, as indicated by the large arrows in **FIG. 3**, causes each vertebra $\mathbf{V_1}$, $\mathbf{V_2}$ to rotate relative to the stabilization element **25**, as accommodated by the flexible portions **18**. Nominally, movement of one vertebra under external load is isolated from the other vertebra as the flexible portion **18** of the bone anchor **10** bends.

The representation in **FIG. 3** illustrates one significant benefit of the present dynamic stabilization system over prior systems. In particular, the center of rotation (CR) for a normal motion segment is represented by the marking $\mathbf{CR_N}$. It is believed that an optimum dynamic stabilization system will emulate the normal movement of the motion segment as accurately as possible, given the limited ways in which the system can be fastened to the spine. Consequently, where the dynamic stabilization system permits rotation in the A/P plane, as represented by the center of rotation marking $\mathbf{CR_N}$, the more optimum system will exhibit a center of rotation as close to the normal center $\mathbf{CR_N}$ as possible. Systems that rely upon providing inter-spinous flexibility, - i.e., those anchored to the transverse process that are connected between adjacent spinous processes via wires or lamina, cables - produce a center of rotation $\mathbf{CR_I}$ that is well remote from the normal center of rotation. Systems that rely upon flexibility at the point

of fixation to the elongated spinal rod or plate have a center of rotation **CR_F** that is essentially along the axis of the elongated rod/plate.

However, the present invention offers a center of rotation **CR_R** that can be is at the surface of the pedicle, and therefor as close as possible to the normal center of rotation as is physically and anatomically possible. The posteriorly positioned centers of rotation **CR_I, CR_F** tend to generate abnormal loading patterns and greater loads on the anterior annulus during normal movements of the spine. The present invention beneficially moves the center of rotation **CR_R** of the instrumented motion segment anteriorly toward the normal center so that the disc experiences more normal loading patterns during flexion and extension of the spine.

In one embodiment of the invention, the dynamic stabilization system relies upon an elongated rod sized to span a length of the spine between two or more vertebrae. The elongated rod can be configured like a variety of known spinal implants and can include a number of surface finishes, such as smooth polish, knurling or threading. Likewise, a number of engagement mechanisms can be provided for connecting the bone anchor **10** to the stabilization element **25**. Thus, the head portion **16** of the anchor may assume a number of configurations, including the configurations shown in **FIGS**. **4a-4c**. The head portion may include an open top connector **30** within which a spinal rod **26** is seated as shown in **FIG**. **4a**. A compression member **31** clamps the rod within the connector **30**. Exemplary connectors of this type are described in U.S. Patent No. 5,545,165 to Biedermann et al. The head portion in **FIG**. **4b** includes a top tightening connector **32** that uses a set screw **33** to clamp the rod **26** within the connector. U.S. Patent No. 5,282,801 to Sherman is directed to an exemplary top tightening mechanism.

Finally, an eyebolt-type connector **34** may be used as shown in **FIG**. **4c**. Connectors of this type are described in U.S. Patent No. 5,246,442 to Ashman et al. The specification and figures of each of these patents are incorporated herein by reference. The details of each of these exemplary constructs are known to

the person of skill in the field of spinal implants. It should be understood that the connectors shown in **FIGS. 4a-4c** can be readily used with the anchor **10**, as well as other connector configurations adapted to engage an elongated spinal rod.

The dynamic stabilization system of the present invention also contemplates implementation using a spinal plate, such as the slotted plate **28** shown in **FIG. 5**. This plate can be of many known configurations, such as the design described in U.S. Patent No. **5,209,751** to Farris et al., the disclosure of which is incorporated herein by reference. As shown in **FIGS. 6a-6b**, the head portion **16** of the bone anchor can assume a number of configurations for engagement with the spinal plate **28**. For instance, as shown in **FIG. 6a**, the head portion may assume a bone screw configuration in which the head **36** of the screw engages the top of the spinal plate **28**. In an alternative embodiment, shown in **FIG. 6b**, the anchor may be in the form of a bone bolt in which an intermediate portion **38** engages the underside of the plate **28**. A threaded stem **39** extends through an opening in the plate for engagement with a nut **40**. The nut thus sandwiches the plate **28** against the intermediate portion **38**. The bone anchor configuration of **FIG. 6a** and the bone bolt configuration of **FIG. 6b** are described further in the '751 Patent to Farris et al.

Again, it should be understood that these configurations for the head portion **16** for engagement to a spinal plate **26** are merely exemplary. The principles of the present invention do not depend upon the type of head portion **16** or the type of stabilization element (rod **26** or plate **28**) used. Any connection configuration can suffice provided that the function of the flexible portion **18** of the bone anchor **10** is not significantly impeded.

Where the bone engaging portion **12** includes bone threads **14**, the bone anchor **10** and/or the head portion **16** must incorporate some feature to allow threading of the anchor into the bone. In the bone anchor configuration **36** of **FIG. 6a** or the bone bolt configuration **38** of **FIG. 6b**, the head portion itself includes features for accepting a driving tool, such as a wrench. The feature may include external flats or an internal hex, for instance. External driving flats can be

provided on the connectors shown in **FIGS. 4a-4c**. Alternatively, an internal driving bore may extend through the head portion **16** and into the engagement portion **12**, with an appropriately sized Allen wrench used to thread the anchor into the bone.

An alternative embodiment of a bone anchor **50** is depicted in **FIG. 7**. This bone anchor includes a bone engaging portion **52** that can include bone engaging threads **54**. Again, as with the anchor **10** discussed above, the bone engaging portion can assume a variety of know configurations adapted for engagement within a spinal motion segment or vertebra. The anchor **50** also includes a head portion **56** that can adopt a number of configurations depending upon the type of stabilization element used for the dynamic stabilization system. For example, the head portion may be configured like the connectors **30**, **32**, **34**, **36** or **38** shown in **FIGS. 4a-4c** and **6a-6b**. For the purposes of illustration, the head portion **56** shown in **FIG. 7** is generally in the form of a bone screw, as depicted in **FIG. 6a**.

In one aspect of this embodiment of the invention, the bone anchor **50** includes a flexible portion **58** interposed between the bone engagement portion **52** and the head portion **56**. Unlike the embodiment of **FIG. 1**, the flexible portion **58** is separate from one or the other, or both, of the engagement portion and the head portion. In other words, in the specific illustrated embodiment the flexible portion **58** is a separate component from the other two portions of the anchor **50**. Alternatively, the flexible portion may be integrated into either the engagement portion or the head portion.

However, in one embodiment, the flexible portion **58** is in the form of a generally cylindrical insert body **68** as shown in **FIG. 8a**. This insert body **68** is sized and shaped to generally conform to the outer configuration of the engagement portion **52** and/or the head portion **56** to present a substantially smooth transition between these portions. In this embodiment, the insert body **68** is formed of a bio-compatible polymeric or elastomeric material. For instance, the material can be PEEK (polyetheretherketone), polyurethane or similar

resilient and flexible materials. Certain bio-compatible "soft" metals, such as Nitinol™ may also be used, taking into account the potential for adverse interaction with the metal of the other portions. The insert body can be formed using conventional techniques for the particular material, such as injection molding.

The choice of material dictates the amount of flexibility for the portion **58**. Moreover, the length of the insert body **68** is also a factor in defining the degree of relative motion permitted by the flexible portion **58**. It is contemplated that a range of pre-determined insert bodies **68** may be made available to the orthopaedic surgeon, with the bodies calibrated by anticipated range of angular motion. One benefit of the embodiment shown in **FIG. 7** is that the bone anchor **50** can be converted into a substantially rigid anchor by replacement of the flexible portion **58** with a substantially rigid spacer having the same size and configuration. Thus, unlike prior arthrodesis systems, the flexibility of each bone anchor used in a dynamic stabilization system can be varied from substantially rigid to very flexible depending upon the patient's pathology and indications. The flexibility of the construct can be established during the implantation surgery by choosing among the range insert bodies. That range of bodies may also include components having varying heights to accommodate differences in vertebral geometry depending upon instrumented vertebral level and patient anatomy.

In one embodiment, the insert body **68** includes interlocking segments **70** that are seated within interlocking notches **72** defined in the engagement portion **52** and head portion **56**. The interlocking segments **70** and notches **72** nominally prevent relative rotation between the three components. In addition, the interlocking elements permit torque transmission through the flexible portion **58** when the engagement portion **52** includes bone engaging threads **54**. More importantly, the interlocking elements **70**, **72** facilitate transmission of bending forces across the flexible portion **58**. The interlocking segments **70** also help keep the construct together under bending loads and act as a fulcrum when load is applied to the engagement portion **52**. It is understood that the engagement

portion 52 can be engaged to the vertebral bone prior to introduction of the insert body 68.

In an alternative embodiment, shown in **FIG. 8b**, the flexible portion **58** is in the form of a spring element **74**. In the illustrated embodiment, the spring element **74** is a coil spring that is interposed between the lower engagement portion **52** and the upper head portion **56**. Preferably, the spring element **74** is affixed to these lower and upper portions in a suitable manner, such as by welding or mechanical fastening. As with the insert body **68**, the flexibility of the spring element **74** can be determined by spring material and dimensions. Preferably, the spring element **74** is formed of a bio-compatible and fatigue-resistant metal, such as stainless steel. The wire diameter and coil dimensions may be adjusted to modify the anticipated flexibility of the flexible portion **58**. Preferably, the outer dimension of the spring element **74** is sized to provide a uniform transition from the adjoining portions **52** and **56** to the flexible portion **58**. Most preferably, the spring element **74** is surrounded by a sheath to prevent bone ingrowth into the spring element.

Both embodiments of the flexible portion **58** shown in **FIGS. 8a-8b** permit relative movement between the engagement portion **52** and head portion **56** in radial-longitudinal planes transverse to the longitudinal axis **L** of the anchor **50**. Unlike the anchor **10** of the previous embodiment in which the relative movement is limited to a single transverse plane, the movement permitted by the flexible portion **58** in the embodiment of **FIG. 7** permits movement in all radial-longitudinal planes about the longitudinal axis **L**.

This range of flexible motion can be modified on the embodiment of **FIG. 8a** by introducing stiffening elements **73** to the insert body. These stiffening elements may be integrally formed with the body itself, such as an injection molded feature in a polymer body. Alternatively, the stiffening elements may be a separate component, such as a metal strip, that is attached to or formed within the insert body **73**. Adding stiffening elements **73** within certain radial-longitudinal planes can limit or prevent bending in that plane, relative to other

radial-longitudinal planes without the stiffening elements. In lieu of stiffening elements, it is contemplated that the insert body **68** can present a non-cylindrical form and even a non-uniform cross-section to adjust bending properties in different radial-longitudinal planes.

Returning to **FIG. 7**, a further aspect of the present embodiment is depicted in which a tensioning element **60** is associated with the bone anchor **50**. In the specific embodiment, the tensioning element **60** is a cable that extends through a cable bore **64** defined through each of the portions of the bone anchor. The cable **60** terminates at its distal end in a retention member **62** that is configured to prevent its passage through the bore **64**. In a specific embodiment, the retention member is in the form of an enlarged head or a ball that bears against the distal tip of the engagement portion **52**. Alternatively, the retention member and engagement portion can be configured so that the retention member is buried within the bone anchor **50**.

As shown in **FIG. 7**, the tensioning cable **60** extends through each of the engagement portion **52**, flexible portion **58** and head portion **56**, exiting the anchor at the proximal end of the head portion. The cable **60** is used to pull the three components together and hold them in compression. Consequently, a cable fixation feature **66** is provided that maintains the cable in tension and the bone anchor components in compression. In a preferred embodiment, the cable fixation feature is a crimp that is crimped around the cable and that bears against the proximal face of the head portion **56**. One type of crimp suitable for the present invention, known as a top-hat crimp, is shown and described in U.S. Patent No. 5,312,410 to Miller et al. The '410, the disclosure of which is incorporated herein by reference, also describes a tensioning apparatus that can be used to draw the cable **60** into tension.

Other forms of cable fixation feature other than the crimp **66** are contemplated by the present invention. The selection of fixation feature is generally contingent on the type of stabilization member **25** to which the bone anchor **50** is engaged. The bone anchor configuration shown in **FIG. 7** is

particularly suited for use with a spinal plate, such as the plate **28** shown in **FIG. 5**. A bone bolt configuration, such as the anchor **78** shown in **FIG. 9** can also implement the flexible portion **58** and tensioning cable **60** just described. The anchor **78** is similar to the bone bolt configuration **38** shown in **FIG. 6b**.

A stabilization system is shown in **FIG. 9** that utilizes two spinal plates **28** adjacent each pedicle of the vertebra **V**. A bone anchor **50** is anchored in each pedicle and is engaged to a corresponding spinal plate **28**. A crimp, such as the crimp fixation feature **66** shown in **FIG. 7**, is used to complete the compression assembly of each bone anchor **50**. Alternatively, as depicted in **FIG. 9**, the two cables **60** from the two anchors **50** can be fastened together, such as by a cable twist **76**. Alternatively, an interlocking configuration using a cable loop and top-hat crimp can be utilized, in a manner similar to that depicted in the '410 Patent discussed above.

Other cable arrangements may be used with the present invention. For instance, the cable **60** can be wrapped and fastened around a spinal rod, such as the rod **26** described above. For instance, the tensioning element **60** may include two cable portions extending upward through the cable bore **64**. The ends of the cable portions can be twisted or crimped together around a spinal, in the manner shown in U.S. Patent No. 5,242,446 to Steffee et al., the disclosure of which is incorporated herein by reference. With this type of cable arrangement, the head portion **56** may be modified to engage a spinal rod while also accommodating the twisted cable portions. Another exemplary cable arrangement for use with a spinal rod is shown in U.S. Patent No. 6,514,255 to Ferree, the disclosure of which is incorporated by reference.

In one aspect of the invention, the amount of flexibility accommodated by the flexible portion **58** may be modified by the amount of tension in the tensioning element **60**, or more particularly, the amount of compression between the components of the anchor **50**. In order to maintain the proper compression over the life of the stabilization implant, it is desirable that the cable be formed of a material that is not susceptible to stretching or loosening over time. Thus, in a

preferred embodiment, the cable is formed of wound filament strands that are pre-stretched. The filaments can be formed from a variety of biocompatible materials, such as stainless steel or some form of polyester.

When the engagement portion **52** of the bone anchor **50** includes threads **54**, the bone anchor must provide some means for driving the anchor into bone. As explained above in connection with the bone anchor **10**, the head portion **56** can be configured for engagement with a known driving tool. However, the interposition of the flexible portion **58** can limit the ability to transmit torque between the head portion **56** and the bone engaging portion **52**. Where the flexible portion includes the insert body **68** and interlocking elements **70**, **72**, torque can be transmitted across the insert body.

In an alternative embodiment, the engagement portion **52** is provided with an internal driving feature at its proximal face **53**. Thus, the proximal face defines a hex recess to receive a hex driving tool. The tool can be used to drive the engagement portion **52** into the bone so that the proximal face **53** is generally flush with the bone surface. Some modification to a standard hex driving tool may be necessary to accept the tensioning cable **60** that extends upward through the cable bore **64**. Once the engagement portion **52** is within the vertebra, the flexible portion **58** and head portion **56** can be successively threaded onto the cable **60** and the cable tensioned and fixed to complete the assembly.

The tension element **60** can also take on the form of a flexible rod having a threaded proximal end that projects outside the head portion **56** when the construct is assembled. A nut is threaded down onto the threaded end of the flexible rod to draw the retention member **62** upward and to compress the portions of the bone anchor **50**. The proximal end of the flexible rod can be enlarged to increase the diameter of the threaded end for greater holding power.

A further embodiment of the invention resides in a bone anchor **80** shown in **FIG. 10**. This anchor includes an engagement portion **82** which, like the anchors **10** and **50** above, includes threads **82** or any other configuration suitable for engagement to the spine or a spinal motion segment. The anchor **80** also

includes a head portion **86**, which includes a threaded post **88** as part of a bone bolt configuration similar to that shown in **FIG**. **6b**. Again, like the prior embodiments the head portion **86** can take on a number of configurations depending upon the nature of the stabilization element.

In accordance with one feature of this embodiment, the anchor **80** is provided with a flexible portion **90** that has a reduced cross-section relative to at least the bone engagement portion **82**. Where the bone anchor is a cylindrical anchor, such as a bone bolt, the flexible portion **90** can have a diameter less than the diameter of the engagement portion. The reduced diameter of the flexible portion determines the amount of flexibility of the portion **90**. In addition, the overall dimension of the flexible portion affects the flexibility. For instance, in the specific embodiment shown in **FIG**. **10**, the flexible portion **90** is elongated. In an alternative embodiment, the flexible portion can have a much more limited axial dimension, such as the circumferential groove configuration **94** shown in **FIG**. **11**.

As with the bone anchor **50**, the flexible portion **90** can permit bending movement in all radial-longitudinal planes transverse to the longitudinal axis **L**. Alternatively, the flexible portion **90** has a modified cross-section – i.e., a cross-section that does not necessarily parallel the shape of the cross-section of the engagement portion **82**. The cross-section of the flexible portion may be altered to control the degree of stiffness in different radial-longitudinal planes. For instance, the flexible portion can be generally elliptical so that the width or thickness in one direction is equal to the width or diameter of the engagement portion in that direction, but the width perpendicular to that direction is less than the engagement portion diameter.

In this preferred embodiment, a sleeve **92** surrounds the flexible portion **90**. The sleeve is intended to prevent bone ingrowth into the reduced cross-section of the flexible portion. In specific embodiment, the sleeve **92** is formed by a polymer molded into the space surrounding the reduced cross-section portion. The surface of the molded sleeve may be tailored to conform to the outer profile of the anchor **80**. Alternatively, the sleeve may be a flexible washer that is

pushed over the exposed head portion and flexible portion of the anchor when it is initially engaged to the motion segment. The sleeve **92** must be flexible enough so that its presence is generally transparent to the bending capabilities of the flexible portion **90**. As a further alternative, the sleeve **92** can be configured to add stiffness to the flexible portion **90** of the bone anchor. With this alternative, a common bone anchor design can be used for most dynamic stabilization constructs, with only the sleeve being changed depending upon the desired flexibility.

As mentioned above, fatigue resistance is an important characteristic for the bone anchor **80**. The strength of the anchor can be enhanced by the material, design and manufacturing approaches noted above. With the bone anchor **80** the flexion point falls within the reduced diameter portion **90**. The reduced diameter in this region can be expected to be more susceptible to fatigue than the remainder of the anchor. As discussed above, material selection for the anchor may impart sufficient fatigue resistance to the reduced diameter portion **90**.

Alternatively, the geometry of the reduced diameter portion may be altered to increase the fatigue limit of that portion of the anchor. In one alternative embodiment, the bone anchor **80** shown in **FIG. 10** can be modified in its transverse cross-section (i.e., the cross-section taken along line A-A of **FIG. 10** as viewed in the direction of the arrows). In particular, a modified bone anchor **80'** includes a shank **82'**, head portion **86'** and threaded post **88'** similar to the like components of the anchor **80**. Furthermore, the intermediate flexible portion **90'** has the same reduced profile as the portion **90** as viewed in **FIG. 10.** However, in this alternative embodiment, the portion **90'** has an increased dimension transverse to the reduced dimension. The portion **90'** is thinner in the plane that defines the flexion point $\mathbf{CR_R}$ for the anchor (i.e., the plane depicted in **FIG. 10**) and thicker in the transverse plane (i.e., the plane depicted in **FIG. 12**). The width or thickness of the portion **90'** in the transverse plane can be increased in proportion to the decrease in thickness in the flexion plane, so that the portion

exhibits a width that extends outside the diameter of the shank **82'** or of the head portion **86'**. Since the flexible portion **90'** is situated outside the pedicle of the vertebra, it is not driven into the bone so the portion can assume a larger non-cylindrical dimension. This provides a secondary benefit of preventing inadvertent countersinking of the flexible portion within the pedicle during insertion.

Another embodiment of the invention resides in a bone anchor as shown in **FIGS. 13-15**. The bone anchor **100** includes a bone engaging portion **102**, a head portion **104** and an intermediate flexible portion **106**. The head portion can be configured as shown in U.S. Patent No. 5,261,912 to Frigg, the disclosure of which is incorporated herein by reference. In particular, the head portion **104** defines a rod receiving channel **108** for top loading of a spinal rod, such as the rod **26**. The base of the channel can include includes features **110** for holding the rod against translation. The channel **108** includes internal threads **112** that are configured to engage a clamping member **120** shown in **FIG. 15**. The clamping member **120** includes an externally threaded boss **122** that engages the internal threads **112** of the channel **108**. The boss **122** defines a surface **123** that bears against the rod within the channel **108** to clamp the rod against the holding features **110**. The clamping member **120** also includes an outer cap **124** that fits around the outside of the head portion **104** to close the clamp and to prevent outward flaring of the head portion when the clamping member is tightened onto the head portion. The clamping member **120** can include an internal feature **126** to engage a driving tool.

Returning to **FIGS. 13** and **14**, the bone anchor **110** includes an intermediate flexible portion **106** that serves the same function as the flexible portions described above. In this embodiment, the flexible portion includes a slot **106** that originates at the head portion **104** and extends longitudinally along the axis **L** of the anchor toward the engagement portion **102** of the anchor. The slot **107** is oriented perpendicular to the channel **108** so that the anchor provides flexibility in the plane that includes the rod **26** and the bone anchor **100**. As with

the above described bone anchors of the present invention, the bone anchor **100** is engaged within a vertebra, and particularly the pedicle of the vertebra, with the flexible portion **106** outside the bone.

It is understood that the bone anchor **100** can include a head portion **104** configured to engage a spinal rod in a different manner, or to engage an elongated plate spanning a portion of the spine. For instance, any of the alternative configurations shown in **FIGS. 4a-4c** can be adapted to the bone anchor **100**. Moreover, the slot **107** may be modified to define a closed slot within the intermediate flexible portion **106** only. In other words, rather than originating at the top of the head portion, as shown in **FIG. 14**, the slot **107** can originate near, and preferably below, the base of the rod channel as represented by the dashed line **109** in **FIG. 14**.

With each of the embodiments of the present invention it is contemplated that each motion segment can be instrumented with a bone anchor having a flexibility tailored to that particular level. For instance, where the dynamic stabilization construct spans several vertebrae, only some of the motion segments may be amenable to use of the dynamic or soft stabilization. Some motion segments may require rigid stabilization, in which case a known rigid bone anchor can be employed if appropriate. Different flexibilities may be incorporated into bone anchors along the length of the spine, and even on opposite sides of the sagittal plane, bearing in mind that a principal goal of the construct is to restore normal loading patterns for the spine.

Certain embodiments of the invention are also well-suited to revision surgeries, where changes to the construct may be necessary months and even years after the initial implantation. Since the preferred construct maintains the flexible portion outside the vertebral bone, it can be accessible in a revision surgery to replace the flexible portion **58** of the bone anchor **50**, for instance.

The dynamic stabilization system of the present invention is well suited as an adjunct to a disc repair procedure. For instance, the intervertebral disc **D** (see **FIG. 3**) may require augmentation or replacement, depending upon the severity of the damage or disease to the disc. Where the disc is intact, it is important to maintain the loading pattern as normal as possible since this loading pattern helps hydrate the disc **D** and flush toxins from the disc.

Devices have been developed for replacement of the intervertebral disc. In some cases, the device is a mechanical device that is configured to mimic the mechanics of the disc motion. In more recent years, the nucleus pulposus of the intervertebral disc has been replaced with a polymer prosthesis that emulates the physical and chemical properties of the disc. In particular, these types of prostheses are intended to preserve or restore the movement and load response of the affected disc as close to the natural disc as possible. One such material is a hydrogel that has similar elastic properties to the natural nucleus pulposus and that shares a similar fluid transport mechanism to the natural disc. This material can be used to replace the entire nucleus pulposus, or to augment the existing nucleus where voids or other defects in the nucleus exist.

Even where the intervertebral disc has been replaced with a mechanical device, or where all or part of the nucleus pulposus has been replaced with a polymer prosthesis, restoration and maintenance of normal spinal segment motion is important. Consequently, it is contemplated that the dynamic stabilization system of the present invention, including bone anchors such as the anchors **10**, **50**, **80** and **100**, can be used in connection with disc/nucleus repair or replacement procedures.

Prior dynamic stabilization systems rely upon flexible elements spanning between transverse processes or laminae. One significant drawback of these types of systems is that they cannot be used for all types of spinal surgical procedures. For instance, in one procedure for the correction of scoliosis, a spinal rod, such as the rod **26** shown in **FIGS. 16a-b**, is bent to a contour **C** and engaged to each vertebra of the deformed spinal column. The rod **26** is then

rotated about its axis in the direction **R** shown in **FIG. 16a** to de-rotate the spine. The resulting spine assumes the more normal configuration and curvature shown in **FIG. 17a-b** in which the lateral curvature has been corrected (**FIG. 17a**) and the normal lordosis and kyphosis has been restored to the spine in the A/P plane (**FIG. 17b**). In many cases, a second rod **26** can be added to the contra-lateral side of the spine to stabilize the construct.

The above mentioned prior dynamic stabilization systems cannot accomplish correction of scoliosis through rod de-rotation because they lack the force-transmission interface with the rotated rod. These prior systems are also unable to maintain a fixed relationship between adjacent vertebrae because the flexible segments span the vertebrae. On the other hand, the bone anchors **10**, **50**, **80** and **100** of the present invention are well-suited to this type of procedure because the anchors can be engaged to a spinal rod for the necessary force transmission. Moreover, the bone anchors of the present invention allow for different degrees of flexibility at each instrumented vertebral level. For instance, as depicted in **FIG. 16a**, the two vertebrae at the superior and inferior ends of the construct may incorporate the flexible bone anchors of the present invention, while the intermediate vertebrae can be instrumented with known rigid fasteners (and in some cases can be fused). Adding dynamic flexibility at the distal ends of long constructs, such as the construct depicted for correction of scoliosis, is believed to reduce the occurrence of "transition syndrome", a condition manifested by accelerated degeneration of the distal vertebrae. due to abnormal loading at distal segments in a rigid construct. The stress concentration present at the interface between the rigid fusion and the flexible natural segments is believed to accelerate the degeneration process. By adding flexible segments, with the ability to vary the stiffness of the segments as described above, the distribution of stress along the spine can be made more uniform.

The present invention offers a similar benefit to a reduction procedure, such as for correction of spondylolisthesis, as depicted in **FIG. 18**. Where a severe slip has occurred, such the slip of the L_5 vertebra shown in **FIG. 18**, one

approach has been to pull the slipped vertebra up to a rigid stabilization member, such as the rod **26**. In this case, a bone anchor **130** is engaged to the flanking spinal elements, such as the $\mathbf{L_4}$ vertebra and the sacrum **S**. Preferably, the anchor engaging the sacrum is a rigid fastener, while the anchors engaging one or both of the vertebrae can be one the bone anchors of the present invention. Since the bone anchors **10**, **50**, **80** and **100** allow force transmission through the anchor, the anchor engaged to the $\mathbf{L_5}$ vertebra is pulled toward the rod **26** to reduce the slip at that vertebra. Again, the prior dynamic stabilization systems cannot accomplish this type of reduction.

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and described in the following written specification. It is understood that no limitation to the scope of the invention is thereby intended. It is further understood that the present invention includes any alterations and modifications to the illustrated embodiments and includes further applications of the principles of the invention as would normally occur to one skilled in the art to which this invention pertains.